

CHAPTER 6

Outpatient dialysis services

R E C O M M E N D A T I O N S

6-1 The Congress should not increase the outpatient dialysis payment rate for calendar year 2015.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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6-2 The Congress should direct the Secretary to:

- include a measure that assesses poor outcomes related to anemia in the End-Stage Renal Disease Quality Incentive Program.
- redesign the low-volume payment adjustment to consider a facility's distance to the nearest facility.
- audit dialysis facilities' cost report data.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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Outpatient dialysis services

Chapter summary

Outpatient dialysis services are used to treat the majority of individuals with end-stage renal disease (ESRD). In 2012, about 370,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,800 dialysis facilities. For most facilities, 2012 is the second year that Medicare paid them using a new prospective payment system (PPS) that includes in the payment bundle certain dialysis drugs and ESRD-related clinical laboratory tests for which facilities and clinical laboratories previously received separate payments. In 2012, Medicare expenditures for outpatient dialysis services in the new payment bundle, including items and services furnished by other providers in prior years, were \$10.7 billion, a 6 percent increase compared with 2011 Medicare dialysis expenditures.

Assessment of payment adequacy

Our payment adequacy indicators for outpatient dialysis services are generally positive.

Beneficiaries' access to care—Measures of the capacity and supply of providers, beneficiaries' ability to obtain care, and changes in the volume of services suggest payments are adequate.

- **Capacity and supply of providers**—Dialysis facilities appear to have the capacity to meet demand. Growth in the number of dialysis treatment

In this chapter

- Are Medicare payments adequate in 2014?
- How should Medicare payments change in 2015?
- Regulatory improvements to the new dialysis PPS

stations has generally kept pace with growth in the number of dialysis beneficiaries.

- ***Volume of services***—Between 2010 and 2012, the number of FFS dialysis beneficiaries and dialysis treatments grew at similar rates (2 percent and 3 percent, respectively). At the same time, the per treatment use of most dialysis injectable drugs, including erythropoiesis-stimulating agents (ESAs) that are used in anemia management, substantially declined. The new dialysis PPS created an incentive for providers to be more judicious about their provision of dialysis drugs. In addition, in 2011, the Food and Drug Administration recommended more conservative ESA dosing.

Quality of care—Using CMS data, we look at changes in quality indicators for the period from 2010 through June 2013. Rates of mortality and emergency department use remained relatively constant, while rates of hospitalization declined. With regard to anemia management, average hemoglobin levels decreased from 11.4 g/dL in 2010 to 10.6 g/dL. Under the new PPS, use of home dialysis, which is associated with improved patient satisfaction and quality of life, increased from 8 percent of beneficiaries to 10 percent.

Providers' access to capital—Information from investment analysts suggests that access to capital for dialysis providers continues to be adequate. The number of facilities, particularly for-profit facilities, continues to increase.

Medicare payments and providers' costs—Our analysis of Medicare payments and costs is based on 2011 and 2012 claims and cost report data submitted by freestanding dialysis facilities to CMS. Under the new PPS, cost per treatment increased by 2 percent between 2011 and 2012, while Medicare payment per treatment increased by 2.3 percent. We estimate that the aggregate Medicare margin was 3.9 percent in 2012 and project that the aggregate Medicare margin will be 2.9 percent in 2014. This projection reflects statutory payment updates and positive regulatory changes that will increase total payments in 2013 and 2014, a reduction in total payments in 2014 due to the statutory drug utilization adjustment, and a small payment reduction in 2013 and 2014 due to the ESRD Quality Incentive Program (QIP). This projection does not consider the impact of the sequester, which would lower the margin by about 2 percentage points.

Regulatory improvements to the new PPS

To improve the ESRD PPS, the Commission recommends that the Congress direct the Secretary to include a measure that assesses poor outcomes related to anemia in the ESRD QIP, redesign the low-volume payment adjustment to consider a low-volume facility's proximity to other dialysis facilities, and audit dialysis

facilities' cost report data. This recommendation addresses three concerns: (1) like any PPS, bundled payments create an incentive for providers to furnish fewer services (covered in the bundled payment) than medically necessary, but the ESRD QIP in 2013 and beyond does not assess the outcomes associated with poorer anemia management that might occur when fewer services are provided; (2) the low-volume payment adjustment is not targeting facilities that might be critical to beneficiary access; and (3) CMS has not yet examined the appropriateness of the costs that facilities include on their cost reports. ■

Dialysis treatment choices

Dialysis replaces the filtering function of the kidneys when they fail. The two types of dialysis—hemodialysis and peritoneal dialysis (PD)—remove waste products from the bloodstream differently. Within these two types of dialysis, patients may select various protocols.

Most dialysis patients travel to a facility to undergo hemodialysis three times per week, although patients can also undergo hemodialysis at home. Hemodialysis uses an artificial membrane encased in a dialyzer to filter the patient's blood. Recent clinical findings have increased interest in more frequent hemodialysis, administered five or more times per week while the patient sleeps, and short (two to three hours per treatment) daily dialysis administered during the day. New research also has increased interest in the use of "every-other-day" hemodialysis; reducing the two-day gap in thrice-weekly hemodialysis may be linked to improved outcomes.

PD, the most common form of home dialysis, uses the lining of the abdomen (peritoneum) as a filter to clear wastes and extra fluid and is usually performed independently in the patient's home or workplace five

to seven days a week. During treatments, a cleansing fluid (dialysate) is infused into the patient's abdomen through a catheter. The dialysate pulls the waste and extra fluid from the patient's blood into the peritoneal cavity, and when the dialysate is drained, the wastes and extra fluids are drained with it. This filling and draining process (an exchange) is done either manually (continuous ambulatory peritoneal dialysis) or using a machine (continuous cycler-assisted peritoneal dialysis).

Each dialysis method has advantages and disadvantages—no one method is best for everyone. People choose a particular dialysis method for many reasons, including quality of life, patients' awareness of different treatment methods and personal preferences, and physician training and recommendations. Some patients switch methods when their conditions or needs change. Although most patients undergo in-center dialysis, home dialysis remains a viable option because of advantages such as increased patient satisfaction, better health-related quality of life, and fewer transportation challenges compared with in-center thrice-weekly dialysis. ■

Background

End-stage renal disease (ESRD) is the last stage of chronic kidney disease and is characterized by permanent irreversible kidney failure. ESRD patients include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and variation in patients' suitability for transplantation, 70 percent of ESRD patients undergo maintenance dialysis (see text box). Patients receive additional items and services related to their dialysis treatments, including dialysis drugs to treat conditions such as anemia and bone disease resulting from the loss of kidney function.¹

In 2012, about 370,000 ESRD beneficiaries on dialysis were covered under fee-for-service (FFS) Medicare and received dialysis from about 5,800 dialysis facilities.² Since 2011, Medicare has been paying facilities using a

new prospective payment system (PPS) that includes in the payment bundle dialysis drugs for which facilities previously received separate payments and services for which other Medicare providers (such as clinical laboratories) previously received separate payments. In 2012, Medicare expenditures for all outpatient dialysis services included in the payment bundle were \$10.7 billion.

Characteristics of fee-for-service dialysis beneficiaries, 2012

Although Medicare generally does not provide disease-specific entitlement, the 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD, including those under age 65. To qualify for the ESRD program, individuals must be fully or currently insured under the Social Security or Railroad Retirement program, entitled to benefits under the Social Security or Railroad Retirement program, or be the spouse or dependent child of an eligible beneficiary. Because of this statutory provision, most of the estimated 445,000

**TABLE
6-1****FFS dialysis beneficiaries are disproportionately young, male, and African American compared with all Medicare FFS beneficiaries, 2012**

	Percent of FFS:	
	Dialysis beneficiaries	All beneficiaries
Age		
Under 45 years	12%	4%
45–64 years	38	14
65–74 years	25	45
75–84 years	18	24
85+ years	7	12
Sex		
Male	54	46
Female	46	54
Race		
White	49	82
African American	36	10
All others	15	8
Residence, by type of county		
Urban	82	77
Rural micropolitan	11	13
Rural, adjacent to urban	5	6
Rural, not adjacent to urban	3	4
Frontier	1	1

Note: FFS (fee-for-service). Urban counties contain a cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, and rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

Source: Data compiled by MedPAC from 2012 claims submitted by dialysis facilities to CMS and the 2012 CMS denominator file.

individuals on maintenance dialysis in 2012 were enrolled in Medicare.³ According to CMS's renal facility survey, about 96 percent of dialysis patients are covered by Medicare.⁴

Most (87 percent) Medicare dialysis beneficiaries have FFS coverage.⁵ The statute prohibits enrollment of individuals with ESRD in Medicare Advantage (MA) plans. However, beneficiaries who were enrolled in a managed care plan before an ESRD diagnosis can remain in the plan after they are diagnosed. In 2012, about 13 percent of dialysis beneficiaries were enrolled in MA

plans; by comparison, about 26 percent of all Medicare beneficiaries were enrolled in MA plans. In 2000, the Commission recommended that the Congress lift the prohibition on ESRD beneficiaries enrolling in MA (Medicare Payment Advisory Commission 2000).

In 2012, a majority of dialysis FFS beneficiaries were enrolled in Part D or had other sources of creditable drug coverage: 77 percent of dialysis FFS beneficiaries were enrolled in Medicare's Part D program, and 12 percent received drug coverage through a retiree drug plan or other source of creditable coverage. By comparison, 53 percent of all FFS beneficiaries were enrolled in the Part D program, and 28 percent received drug coverage through a retiree drug plan or other source of creditable coverage. About three-quarters of dialysis beneficiaries with Part D coverage received the low-income subsidy. About 11 percent of dialysis FFS beneficiaries in 2012 either had no Part D coverage or had coverage less generous than Part D's standard benefit.

Compared with all Medicare FFS beneficiaries, FFS dialysis beneficiaries are disproportionately young, male, and African American, and they are more likely to reside in urban areas (Table 6-1). In 2012, 75 percent of FFS dialysis beneficiaries were less than 75 years old, 54 percent were male, and 36 percent were African American. By comparison, of all FFS Medicare beneficiaries, 63 percent were less than 75 years old, 46 percent were male, and 10 percent were African American. A greater share of dialysis beneficiaries reside in urban areas compared with all FFS beneficiaries (82 percent vs. 77 percent, respectively).

Between 2001 and 2011, the rate (or incidence) of new ESRD cases decreased by 0.5 percent per year, from 374 per million people to 357 per million people (United States Renal Data System 2013).⁶ Since 2009, the rate of new ESRD cases has declined by 3 percent per year. This decline is seen across all races and ethnicities (White, African American, Asian, Native American, and Hispanic) and age groups, with the exception of young individuals (19 years or younger).⁷ In 2012, we estimate that approximately 83,000 FFS dialysis beneficiaries were new to dialysis, and nearly half (47 percent) of them were under age 65 and thus entitled to Medicare based on ESRD (with or without disability).⁸

Data from the mid-1990s through 2010 suggest a trend toward initiating dialysis earlier in the course of chronic kidney disease (United States Renal Data System 2013). The proportion of patients with higher levels of residual kidney function steadily increased between 2000 and 2010,

from 7 percent to 16 percent.⁹ In 2011, the share of those patients decreased modestly to 15 percent. Researchers have questioned this early initiation of dialysis in those with late-stage chronic kidney disease, concluding that it was not associated with improved survival or clinical outcomes (Cooper et al. 2010, Evans et al. 2011, Kazmi et al. 2005, Stel et al. 2009, Traynor et al. 2002).

To help pay for Part A and Part B cost sharing, some FFS beneficiaries have private or other public coverage that supplements the Medicare benefit package. Compared with all FFS beneficiaries, FFS dialysis beneficiaries are more likely to be dually eligible for Medicare and Medicaid (17 percent vs. 47 percent, respectively) and less likely to receive coverage from private sources (70 percent vs. 50 percent, respectively) (these coverage categories are not mutually exclusive). According to the Medicare Current Beneficiary Survey, in 2011, about 15 percent of dialysis FFS beneficiaries lacked any public or private supplemental coverage. Since 1997, the American Kidney Fund has maintained a Health Insurance Premium Program that helps pay dialysis patients' health insurance premiums, including Medicare Part B premiums.¹⁰

According to data from Medicare's denominator file, in 2012, Medicare was the secondary payer (for Part A and Part B) for 9 percent of FFS dialysis beneficiaries insured by an employer group health plan (EGHP) at the time they were diagnosed with ESRD. Under these circumstances, the EGHP is the primary payer for the first 33 months of care (as long as the individual maintains the EGHP coverage). EGHPs include health plans in which beneficiaries are enrolled through their own employment or through a spouse's or parent's employment before becoming eligible for Medicare through an ESRD diagnosis.

Since 2011, CMS has paid most dialysis facilities under the new dialysis PPS

To treat ESRD, dialysis beneficiaries receive care from two principal providers: (1) the physicians (typically nephrologists) who prescribe and manage the provision of dialysis and establish the beneficiary's plan of care, and (2) facilities that provide dialysis treatments in a dialysis center or support and supervise the care of beneficiaries on home dialysis. Medicare uses different methods to pay for ESRD clinician and facility services. Clinicians receive a monthly capitated payment established in the Part B physician fee schedule for outpatient dialysis-related management services, which varies based on the number of visits per month, the beneficiary's age, and whether the beneficiary receives dialysis in a facility or at home. While

this chapter focuses on Medicare's payments to facilities, it is important to recognize that facilities and clinicians collaborate to care for dialysis beneficiaries.

To improve the efficiency of dialysis facilities, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) mandated that CMS implement a new PPS in 2011 for dialysis facilities that includes in the payment bundle dialysis drugs, laboratory tests, and other ESRD-related items and services that were previously separately billable. MIPPA also mandated that in 2012 CMS implement a pay-for-performance program. MIPPA's provisions are consistent with the Commission's recommendation to modernize the outpatient dialysis payment system (Medicare Payment Advisory Commission 2001). We contended that Medicare could provide incentives for controlling costs and promoting quality care by broadening the payment bundle (to include drugs, laboratory services, and other commonly furnished items that providers formerly billed separately) and by linking payment to quality. The new PPS is designed to create incentives for facilities to provide services more efficiently by reducing previous incentives inherent in the former payment method to overutilize drugs. In 2011, most dialysis facilities (about 93 percent) elected to be paid under the new PPS instead of the four-year transition rate.¹¹

Under both the prior and current payment methods, Medicare pays facilities for a single dialysis treatment by using a prospective payment. However, the current payment method differs from the former one in the following ways: it (1) uses a broader payment bundle that includes injectable drugs and clinical laboratory services that were previously billable separately, (2) sets payment using a greater number of patient-level payment adjusters, (3) provides an outlier payment for high-cost beneficiaries, (4) increases the base rate by a low-volume adjustment for certain low-volume facilities, and (5) links facilities' payments to the quality of care they provide. The Commission's *Payment Basics* provides more information about Medicare's methods for paying for outpatient dialysis services (available at http://medpac.gov/documents/MedPAC_Payment_Basics_13_dialysis.pdf).

In 2014, the last year of the four-year transition to the new payment method, 100 percent of Medicare payment for all dialysis facilities is based on the new payment method. The 2014 base prospective payment is \$239.02 per treatment, a difference of 0.5 percent compared with the 2013 base rate of \$240.36 per treatment. This rate change between 2013 and 2014 primarily reflects two statutory

Section 632 of the American Taxpayer Relief Act of 2012

The American Taxpayer Relief Act of 2012 mandates that for dialysis services furnished on or after January 1, 2014, the Secretary must reduce the end-stage renal disease (ESRD) prospective payment system (PPS) base rate to reflect the change in per patient use of ESRD drugs and biologics between 2007 and 2012. The law requires that the Secretary, in making this reduction, take into account the most recently available data on average sales prices and changes in prices for drugs and biologics reflected in the ESRD market basket.

CMS calculated the change in drug use between 2007 and 2012 and the total drug utilization adjustment (reduction) per treatment by:

- determining 2012 per treatment use of ESRD drugs using 2012 claims included in the National Claims History file as of June 30, 2013.
- determining 2007 per treatment use of ESRD drugs as established in the 2011 ESRD PPS final rule.
- applying 2014 ESRD drug prices to the 2007 and 2012 per treatment use of ESRD drugs. To derive 2014 prices, the agency inflated 2011 drug prices by 7.64 percent. This inflation factor is based on the 2013 and 2014 ESRD market basket (net of

the productivity adjustment) and the wage index budget-neutrality and home dialysis training add-on factors.

- determining the per treatment difference (in 2014 prices) between the per treatment amounts for 2012 (\$51.17) and 2007 (\$83.96).
- adjusting the net difference between the 2007 and 2012 per treatment use of ESRD drugs (\$32.79) by the same factors that were used to establish the 2011 ESRD PPS rate: the 5.93 percent standardization factor, the 1 percent outlier adjustment factor, and the 2 percent adjustment factor mandated by the Medicare Improvements for Patients and Providers Act of 2008. This calculation results in a total drug reduction of \$29.93 per treatment.

CMS will phase in the drug utilization adjustment over a three- to four-year transition period. For 2014 and 2015, CMS will implement the adjustment by offsetting the payment update and other effects by a portion of the drug utilization reduction amount necessary to create an overall impact of zero percent compared with the previous year's total payments. For 2014, the drug use reduction is \$8.16 per treatment. ■

provisions: (1) MIPPA requires the Secretary to increase the dialysis PPS rate by the rate of increase in the ESRD market basket, reduced by a productivity adjustment; and (2) the American Taxpayer Relief Act (ATRA) of 2012 requires, for services furnished on or after January 1, 2014, the Secretary to reduce the ESRD PPS base rate to reflect the change between 2007 and 2012 in the per patient utilization of dialysis drugs and biologics (see text box summarizing the ATRA provision and the Secretary's calculations).

Are Medicare payments adequate in 2014?

To address whether payments for 2014 are adequate to cover the costs that efficient providers incur and how much

providers' costs should change in the update year (2015), we examine several indicators of payment adequacy.¹² We assess beneficiaries' access by examining the capacity of dialysis providers and changes over time in the volume of services provided, quality of care, providers' access to capital, and the relationship between Medicare's payments and providers' costs. Most of our payment adequacy indicators for dialysis services are positive:

- Provider capacity is sufficient.
- Volume growth as measured by the number of dialysis treatments has kept pace with growth in the number of beneficiaries.
- Some quality measures show improvement.
- Provider access to capital is sufficient.

**TABLE
6-2****Increasing number and capacity of freestanding, for-profit, and chain organizations**

	2012				Average annual percent change			
	Total number of FFS treatments (in millions)	Total number of facilities	Total number of stations	Mean number of stations	Number of facilities		Number of stations	
					2007–2012	2011–2012	2007–2012	2011–2012
All	43.3	5,800	103,100	18	3%	2%	4%	2%
Percent of total								
Freestanding	93%	91%	93%	18	4	3	4	3
Hospital based	7	9	7	14	–4	–10	–3	–8
Location, by type of county								
Urban	84	79	83	19	4	2	4	2
Rural micropolitan	11	13	12	16	2	0	3	1
Rural, adjacent to urban	3	5	4	13	3	1	4	2
Rural, not adjacent to urban	2	3	2	12	3	2	3	1
Frontier	0.2	0.6	0.4	10	–1	0	2	8
For profit	89	85	86	18	4	3	5	3
Nonprofit	11	15	14	17	–2	–7	–1	–5
Two largest dialysis organizations	75	70	72	18	7	10	7	10
All others	25	30	28	17	–3	–13	–2	–14

Note: FFS (fee-for-service). Urban counties contain a cluster of 50,000 or more people, rural micropolitan counties contain a cluster of 10,000 to 50,000 people, rural adjacent counties are adjacent to urban areas and without a city of at least 10,000 people, and rural nonadjacent counties are not adjacent to an urban area and do not have a city with at least 10,000 people. Frontier counties have six or fewer people per square mile. Totals may not sum to 100 percent due to rounding.

Source: Compiled by MedPAC from the 2007, 2011, and 2012 Dialysis Compare database from CMS and 2012 claims submitted by freestanding and hospital-based dialysis facilities to CMS.

- The 2012 aggregate Medicare margin is estimated at nearly 4 percent, and the projected 2014 Medicare margin is nearly 3 percent.

Beneficiaries' access to care: Indicators continue to be favorable

Our analysis of access indicators—including the capacity of providers to meet beneficiary demand and changes in the volume of services—shows that beneficiaries' access to care remains favorable.

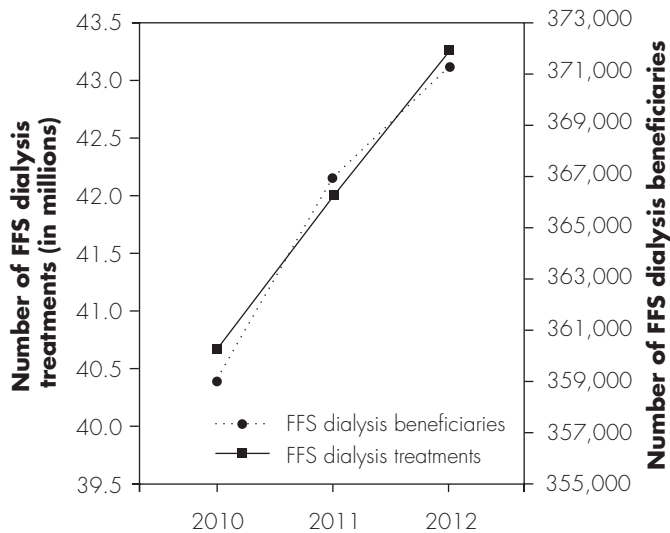
Capacity has kept pace with patient demand

From 2007 to 2012, the total number of facilities increased annually by 3 percent, and their capacity to provide care—as measured by dialysis treatment stations—grew 4 percent annually (Table 6-2). During this period, the capacity of facilities that were freestanding and for

profit each grew by 4 percent and 5 percent per year, respectively. By contrast, annual growth in the capacity of facilities that were hospital based and nonprofit decreased (–3 percent and –1 percent, respectively). Between 2007 and 2012, the capacities of urban and rural facilities grew at similar rates.

Trends in supply between 2011 and 2012 are generally similar to those between 2007 and 2012, except for the growth in facilities and stations associated with the two largest dialysis organizations. As a consequence of recent acquisitions, their average annual growth rate between 2011 and 2012 exceeded their average annual growth between 2007 and 2012.¹³

Growth in the number of dialysis stations and dialysis beneficiaries suggests that provider capacity kept up with demand for care between 2007 and 2012. During

**FIGURE
6-1****Similar growth rates for dialysis
treatments and beneficiaries
between 2010 and 2012**

Note: FFS (fee-for-service).

Source: MedPAC analysis of 2010–2012 claims submitted by dialysis facilities to CMS.

this period, the 4 percent annual growth in the number of treatment stations was faster than the 2 percent average annual growth in the number of FFS dialysis beneficiaries.

Providers of outpatient dialysis services

In 2012, there were about 5,800 dialysis facilities in the United States (Table 6-2, p. 149). Since the late 1980s, for-profit, freestanding facilities have provided the majority of dialysis treatments (Rettig and Levinsky 1991). In 2012, freestanding facilities furnished 93 percent of FFS treatments and for-profit facilities furnished about 89 percent. Between 1997 and 2012, the share of facilities that is for profit and freestanding increased from 66 percent to 85 percent. In 2012, the distribution of facilities located in urban and rural areas was generally consistent with where FFS dialysis beneficiaries lived.

Chain organizations dominate this sector, which has seen significant industry consolidation.¹⁴ In 2005 and 2006, the four largest dialysis chains merged into two chains (here referred to as the two largest dialysis organizations). By 2012, they accounted for about 70 percent of all facilities.

In 2012, the two largest dialysis organizations accounted for the majority of facilities in both rural and urban areas.

In rural areas, 68 percent of facilities were affiliated with the two largest dialysis organizations, 20 percent were affiliated with other freestanding facilities, and 12 percent were hospital based. In urban areas, about 71 percent of facilities were affiliated with the two largest dialysis organizations, 22 percent were affiliated other freestanding facilities, and 8 percent were hospital-based.

In addition to operating most dialysis facilities, the two organizations are each vertically integrated. One is the leading supplier of dialysis products, such as hemodialysis machines and dialyzers, and develops and distributes renal-related pharmaceutical products (e.g., phosphate binders) (Fresenius Medical Care AG & Co. KGaA 2006). Both organizations operate an ESRD-related laboratory, a pharmacy, and one or more centers that provide vascular access services; they provide ESRD-related disease management services; and they operate dialysis facilities internationally.

**Type of facilities that closed and their effect on
beneficiaries' access to care**

Each year, we assess the type of facilities that closed and whether certain groups of Medicare dialysis beneficiaries are disproportionately affected by facility closures. Using claims submitted by facilities to CMS and CMS's Dialysis Compare database, the Provider of Service file, and the ESRD facility survey, we compare the characteristics of beneficiaries treated by facilities that closed in 2011 with those in facilities that furnished dialysis in 2011 and 2012.

On net, between 2011 and 2012, the number of dialysis treatment stations—a measure of providers' capacity—increased by 2 percent. Compared with facilities that treated beneficiaries in both years, facilities that closed in 2011 (about 65 units) were more likely to be hospital based and nonprofit, which is consistent with long-term trends in supply (Table 6-2, p. 149). As measured by the number of dialysis treatment stations, closed facilities were smaller than facilities in 2011 and 2012 (14 stations vs. 18 stations, respectively). Compared with the distribution of facilities in business both years, a greater proportion of facilities that closed were in rural areas. However, closed rural facilities accounted for only 2 percent of all rural facilities in both years.

About 3,300 dialysis beneficiaries were affected by facility closures in 2012. Our analysis found that racial minority groups and poorer patients (as measured by Medicaid eligibility) were not disproportionately affected by these

**TABLE
6-3**
Use per treatment of most dialysis drugs declined between 2010 and 2012

Dialysis drug	Mean units per treatment*						Aggregate percent change	
	2007	2008	2009	2010	2011	2012	2007-2012	2010-2012
ESAs								
Erythropoietin	5,532	5,099	5,243	5,214	4,033	3,106	-44%	-40%
Darbepoetin alfa	1.52	1.42	1.41	1.26	0.93	0.67	-56	-47
Iron agents								
Sodium ferric gluconate	0.39	0.39	0.30	0.15	0.16	0.17	-57	15
Iron sucrose	12.3	13.0	14.7	16.0	15.8	12.7	3	-21
Ferumoxylol**	N/A	N/A	N/A	0.8	0.9	0.02	N/A	-97
Vitamin D agents								
Paricalcitol	2.3	2.7	2.7	2.3	1.6	1.4	-39	-38
Doxercalciferol	0.8	0.7	0.7	0.9	1.1	1.2	50	38
Calcitriol	0.16	0.10	0.12	0.13	0.10	0.06	-63	-55
Antibiotics								
Daptomycin	0.097	0.163	0.216	0.217	0.183	0.171	76	-21
Vancomycin	0.029	0.021	0.024	0.024	0.024	0.022	-27	-11
Other drugs								
Levocarnitine	0.017	0.015	0.013	0.010	0.005	0.004	-78	-61
Alteplase	0.023	0.022	0.023	0.020	0.012	0.008	-67	-62

Note: ESA (erythropoiesis-stimulating agent), N/A (not available). Individual units per treatment are rounded; the aggregate percent change is calculated using unrounded units per treatment.

*Each drug reported using its own drug units.

**Drug use not available because drug not marketed in the United States in 2007, 2008, and 2009.

Source: MedPAC and Acumen analysis of Medicare claims submitted by dialysis facilities to CMS between 2007 and 2012.

closures. Beneficiary groups who were disproportionately affected included patients who were White, older, and residing in rural areas. Our analysis of 2011 and 2012 claims data suggests that affected beneficiaries were able to obtain care at other facilities.

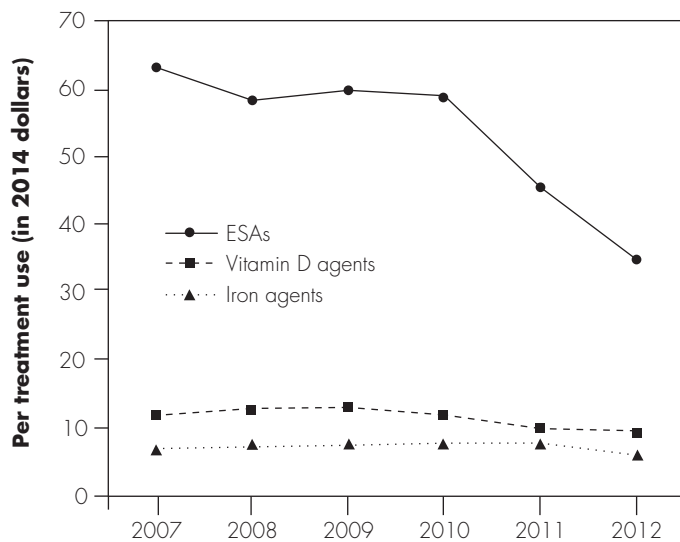
Volume of services

To assess changes in the volume of dialysis services, we examined recent trends in the number of dialysis treatments provided to beneficiaries and in the use of injectable drugs administered during dialysis.

Similar growth rates for dialysis treatments and beneficiaries between 2010 and 2012 Between 2010 and 2012, dialysis treatments grew at an average annual rate that kept pace with growth in the number of FFS dialysis beneficiaries (Figure 6-1). During this period, the number of dialysis treatments grew at an average rate of 3 percent per year, while the number of dialysis beneficiaries grew at an average rate of 2 percent per year.

Use of most dialysis drugs declined between 2010 and 2012 Because CMS based the bundled payment rate in the new PPS on a per treatment basis and based the rate on 2007 use data, we examined changes between 2007 and 2012 (the most current year for which complete data are available) in the use per treatment for the leading 12 dialysis drugs and aggregated them into 4 therapeutic classes—erythropoiesis-stimulating agents (ESAs), iron agents, vitamin D agents, and antibiotics.¹⁵ We also examined changes in the use of drugs between 2010, the year before the start of the new PPS, and 2012.

Between 2007 and 2012, the use of most dialysis drugs declined. During this period, use of eight drugs declined while three increased (ferumoxylol was not marketed in the United States in 2007) (Table 6-3). Per treatment dose of both ESAs (the leading dialysis drug class in use under the prior payment method) declined—erythropoietin by 44 percent and darbepoetin alfa by 56 percent.¹⁶ The Food and Drug Administration (FDA) changed the ESA label in

**FIGURE
6-2****Reduction in drug use by
drug class, 2007–2012**

Note: ESA (erythropoiesis-stimulating agent). Per treatment use is estimated for each drug by dividing total units of that drug by total dialysis treatments and multiplying by CMS's estimated 2014 prices published in CMS's proposed rule for the end-stage renal disease prospective payment system for 2014. ESAs include erythropoietin and darbepoetin; vitamin D agents include calcitriol, doxercalciferol, and paricalcitol; iron agents include iron sucrose, sodium ferric gluconate, and ferumoxytol.

Source: MedPAC and Acumen analysis of 2007–2012 Part B claims submitted by freestanding and hospital-based facilities and the 2014 CMS proposed rule.

March 2007, which contributed to the decline in ESA units per treatment between 2007 and 2008.¹⁷

However, most of the decline in the use of dialysis drugs has occurred since 2010. For example, between 2010 and 2012, the mean per treatment units of both ESAs declined—erythropoietin by 40 percent and darbepoetin alfa by 47 percent (Table 6-3, p. 151). In 2011 and 2012, the first two years of the new PPS, per treatment use declined for all drugs except two—sodium ferric gluconate and doxercalciferol. The new PPS increased the incentive for providers to be more judicious in providing dialysis drugs since they are included in the payment bundle (and thus are a cost center). Under the prior payment method, dialysis drugs were paid according to the number of units of the drug administered (and thus were a profit center); in other words, the more units of a drug provided, the higher the Medicare payment. For ESAs, some of this decline may also have stemmed from clinical evidence that found that higher doses of these drugs led to increased risk of

morbidity and mortality, which resulted in the FDA's changing the ESA label in June 2011.

To measure use by drug class, we took the number of units of a drug provided and multiplied it by the 2014 Medicare price estimated by CMS. On a per treatment basis, use of ESAs, iron and vitamin D agents, and antibiotics was 38 percent lower in 2012 than in 2007. By drug class, on a per treatment basis, between 2007 and 2012 the use of ESAs, injectable iron agents, and vitamin D agents declined by 45 percent, 14 percent, and 19 percent, respectively (Figure 6-2). Use of antibiotics during this period increased by 5 percent (not shown in Figure 6-2). Our results are similar to those that CMS published in the proposed ESRD payment rule for 2014.

Quality of care: The impact of the new PPS

This year's quality analysis focuses on changes in quality indicators since CMS implemented the new payment method and uses CMS's monthly monitoring data (Centers for Medicare & Medicaid Services 2013a). From 2010 through June 2013, rates of mortality and emergency department use have remained relatively unchanged, while hospitalization rates have modestly declined. Regarding anemia management, average hemoglobin levels declined. Under the new PPS, use of home dialysis, which is associated with improved patient satisfaction and quality of life, has increased modestly from 8 percent of beneficiaries to 10 percent.

In this section and the online Appendix 6-A (available at <http://www.medpac.gov>), we examine the multiple factors that affect access to kidney transplantation. The procedure is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality of life outcomes, and demand far outstrips supply. Our conclusion remains unchanged from last year regarding trends in key dialysis quality measures for the most recent five-year period that data are available: While some quality measures show progress, such as vascular access management, others need improvement.

Quality under the new PPS

Compared with 2010, the proportion of dialysis beneficiaries between January 2011 and June 2013 who died or used emergency department services has remained constant, while the proportion of beneficiaries hospitalized has declined (Figure 6-3). Specifically, the monthly proportion of beneficiaries who:

- died averaged 1.7 percent per month in 2010 and 1.6 percent per month in the following years.
- used the emergency department averaged 10.7 percent per month in 2010, 10.5 percent in 2011, and 10.7 percent in the following years.
- were hospitalized steadily declined each year between January 2010 and June 2013 from an average of 14.3 percent per month to 14 percent, 13.4 percent, and 13.1 percent, respectively. This finding is not unexpected given the trend of declining inpatient admissions for all Medicare FFS beneficiaries during this period.

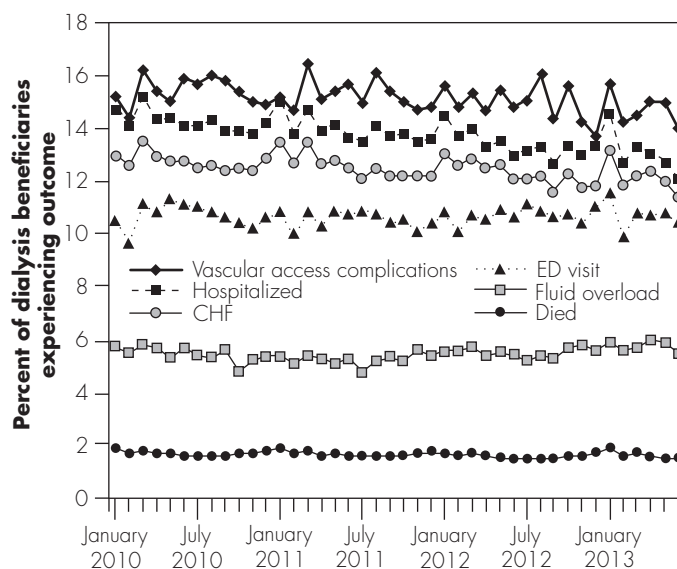
Between January 2010 and June 2013, the percent of hemodialysis beneficiaries who experienced a vascular access complication declined, from an average 15.4 percent per month to 15.3 percent in 2011, 15 percent in 2012, and 14.7 percent in 2013 (Figure 6-3). This trend is consistent with the long-term trend in increased use of the recommended type of vascular access (reported in online Appendix 6-B, available at <http://www.medpac.gov>).

CMS also gathered data on the monthly incidence of common ESRD-related comorbidities including congestive heart failure (CHF) and fluid overload (Figure 6-3). Between 2010 and the first six months of 2013, the share of beneficiaries with a CHF diagnosis modestly declined. The share of beneficiaries with a fluid overload diagnosis remained steady between 2010 and 2012 and increased in the first six months of 2013 (Figure 6-3).

Under the new PPS, management of anemia, as assessed by the declining use of ESAs per treatment, changed (Figure 6-1, p. 150). The indicators that CMS uses to monitor the outcomes associated with anemia management include median hemoglobin levels, incidence of cardiovascular events, and blood transfusions (Centers for Medicare & Medicaid Services 2013a). From January 2010 through June 2013, average monthly hemoglobin levels fell from 11.4 g/dl to 10.6 g/dL.¹⁸ Lower hemoglobin levels are generally associated with lower use of ESAs, while higher hemoglobin levels are associated with higher use of ESAs. The cumulative share of beneficiaries experiencing negative cardiovascular outcomes—stroke, acute myocardial infarction, and heart failure—associated with higher ESA use generally declined from 2007 through June 2013. According to CMS, these declines were gradual, began before implementation of the new PPS, and generally continued under the new PPS. CMS reports that the proportion

FIGURE 6-3

Changes in key outcomes for dialysis beneficiaries, 2010–2013



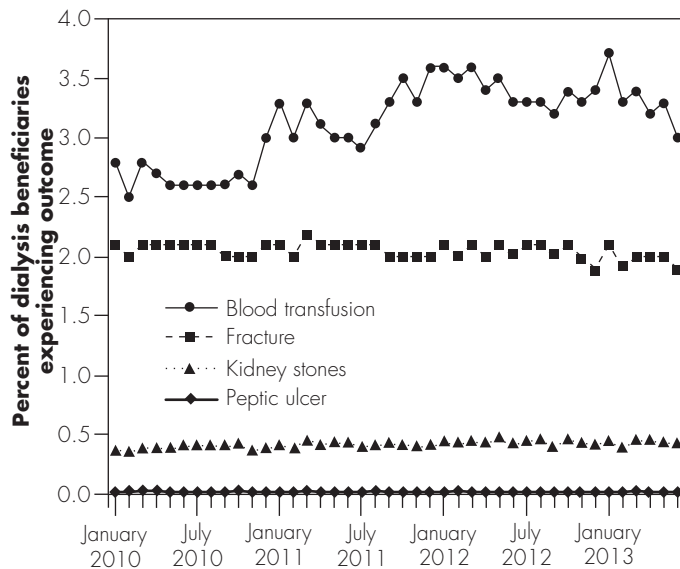
Note: ED (emergency department), CHF (congestive heart failure). Data are compiled on a monthly basis by CMS.

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

of dialysis beneficiaries receiving blood transfusions increased in 2011.¹⁹ Each year from January 2010 through June 2013, the proportion of beneficiaries (in a given month) receiving a blood transfusion averaged 2.7 percent, 3.2 percent, 3.4 percent, and 3.3 percent, respectively (Figure 6-4, p. 154).²⁰

CMS also gathered indicators to assess the management of bone and mineral disease disorders, including fractures, kidney stones, and peptic ulcers. Between January 2010 and June 2013, outcomes for these disorders remained at about the same level (Figure 6-4, p. 154).

Regarding home dialysis, each year from January 2010 through June 2013, CMS reports that the share of beneficiaries dialyzing at home steadily increased from a monthly average of 8.3 percent to 8.9 percent, 9.5 percent, and 9.9 percent, respectively (Figure 6-5, p. 155). Between 2000 and 2009, United States Renal Data System (USRDS) data show that use of home dialysis among all dialysis patients remained relatively constant, ranging from 8 percent to 9 percent. Between 2010 and 2011, USRDS data, like CMS's findings, show that home dialysis use increased (United States Renal Data System 2013).

**FIGURE
6-4****Changes in anemia and
bone and mineral disease
management, 2010–2013**

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

While we are encouraged by this modest increase in use of home dialysis under the PPS, we are concerned that the differences by race remain unchanged. Our analysis suggests that between 2009 and 2012, the proportion of home dialysis beneficiaries who were African American remained at 26 percent each year, while African Americans comprised about 36 percent of all dialysis beneficiaries in those years.

Access to kidney transplantation

Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality of life outcomes (see online Appendix 6-A, available at <http://www.medpac.gov>). However, demand for kidney transplantation exceeds supply. Researchers have shown that kidney transplantation rates differ by patients' demographic and socioeconomic characteristics. Several patient, physician, and system factors affect access to kidney transplantation, including the clinical allocation process and donation rates; patients' health literacy, clinical characteristics, lifestyle, preferences, and beliefs; educational efforts provided by facility staff and clinicians who treat dialysis patients;

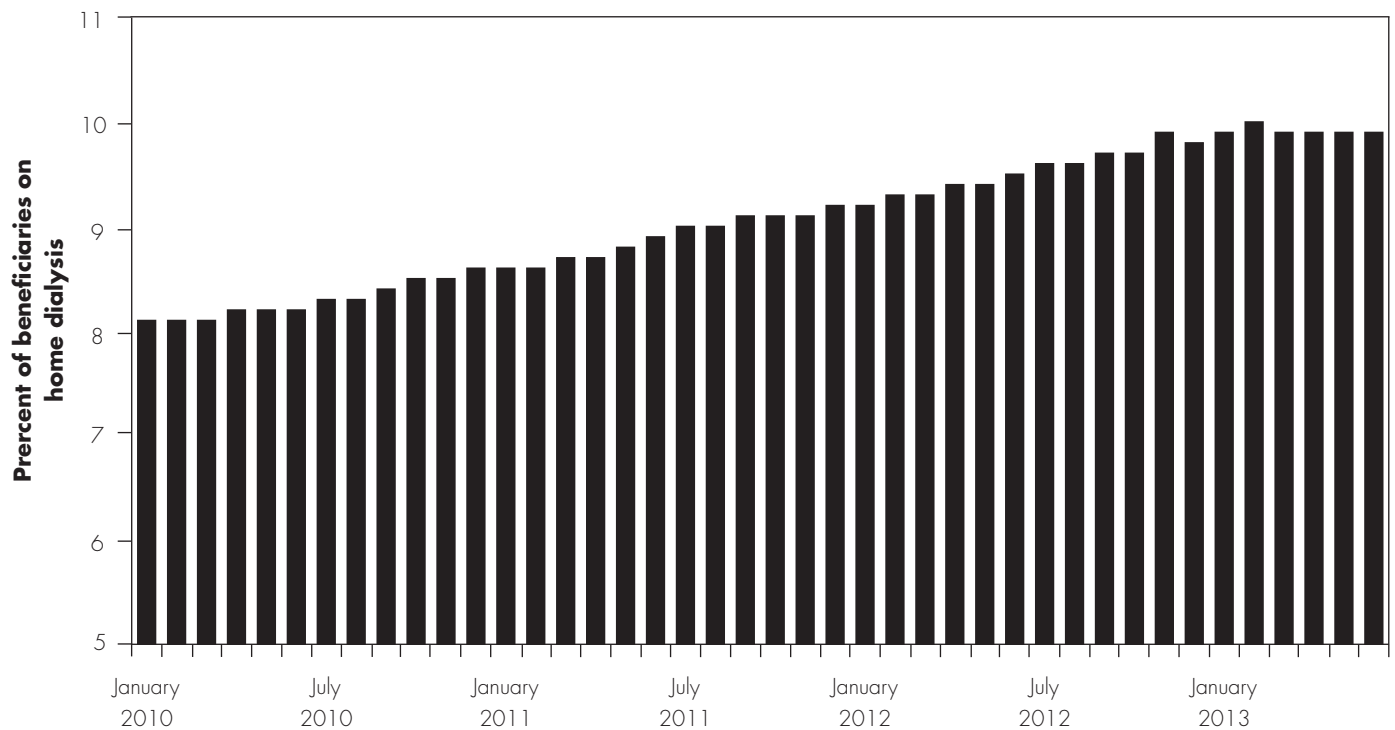
clinician referral for transplant evaluation at a transplant center; and transplant center policies.

There is particular concern about access to kidney transplantation for African Americans because they are less likely than Whites to receive kidney transplants despite their fourfold greater likelihood of developing ESRD. According to Ephraim and colleagues, the lower rates of kidney transplantation for African Americans are associated with multiple factors, including immunological incompatibility with deceased donor kidneys; lower rates of referral for transplantation; lower rates of cadaver kidney donation; less access to health care; and lack of knowledge and suboptimal discussions about kidney transplantation among recipients, their families, and health care providers (Ephraim et al. 2012).

There is a growing focus on the importance of educating patients about their treatment options. MIPPA added kidney disease education (KDE) services as a Medicare Part B–covered benefit for beneficiaries diagnosed with stage IV chronic kidney disease (the stage before end-stage renal disease) who have a referral from the physician managing their kidney condition. Beginning in 2010, CMS began to pay for a lifetime maximum of six education sessions per beneficiary. Few beneficiaries were provided KDE services in 2011 and 2012. We found that about 4,200 beneficiaries received this service in each year, and Medicare KDE spending in 2011 and 2012 was nearly \$645,000 and \$675,000, respectively. KDE services were most frequently provided by nephrologists, nurse practitioners, or physician assistants in an office setting.²¹ This analysis used 100 percent of 2011 and 2012 carrier and outpatient claims submitted for KDE services.

The use of shared decision making has the potential to help patients weigh their options—including whether to initiate dialysis, undergo in-center or home dialysis, and be considered for kidney transplantation. In situations with multiple clinically appropriate options, shared decision making is a process in which clinicians share relevant information about all the options, patients share their preferences and values, and the two parties arrive at a decision that incorporates the expertise of both parties.

Expanding CMS's Dialysis Compare public website to include performance measures on kidney transplantation might be another opportunity to enhance beneficiary awareness. The website permits beneficiaries and their families to find and compare information about dialysis facilities but does not provide facility-level performance

**FIGURE
6-5****Changes in the use of home dialysis, 2010–2013**

Source: CMS's end-stage renal disease prospective payment system overview of 2011–2013 claims-based monitoring program.

measures on access to kidney transplantation. CMS, through its contractor, has developed such a measure—a standardized transplantation ratio—which assesses the ratio of the actual number of transplants at a facility to the expected number, adjusted for patient age.²²

Five-year trends in dialysis quality

For the period from 2007 to 2011, we found the following trends in key quality measures:

- The proportion of patients receiving adequate dialysis remained high, and improvements were made in the use of the recommended type of vascular access for hemodialysis patients and in the management of patients' nutritional status.
- In anemia management, the proportion of patients with high hemoglobin levels has decreased with the decreased use of ESAs beginning in 2010.
- The proportion of dialysis patients accepted on the kidney transplant waiting list has modestly increased, but the rate of kidney transplantation among dialysis patients has declined (see on-line Appendix 6-B, available at <http://www.medpac.gov>).

Providers' access to capital: Growth trends suggest access is adequate

Providers need access to capital to improve their equipment and open new facilities so they can accommodate the growing number of patients requiring dialysis. The two largest dialysis organizations, as well as other renal companies, appeared to have adequate access to capital in 2012 and 2013. For example:

- In 2012, DaVita completed its acquisition of HealthCare Partners for roughly \$4.4 billion. HealthCare Partners runs medical groups and physician networks in California, Florida, and Nevada; has 700 employed physicians and a network of 8,300 independent doctors; is one of the Pioneer Accountable Care Organizations; and is part of the accountable care organization (ACO) pilot project for people covered by Anthem Blue Cross.
- In 2013, Fresenius Medical Care NA acquired Shiel Medical Laboratory Inc., expanding services to the New York City area.
- In 2013, Fresenius announced that it is partnering with the ApolloMed ACO to provide integrated health care management for patients with ESRD.

- In 2013, DaVita HealthCare and Berkshire Hathaway entered into an agreement under which Berkshire would not increase its stake in the company above 25 percent. Berkshire is DaVita's largest shareholder with a stake of about 17 percent (Associated Press 2013). Such an investment suggests the financial attractiveness of the company and the positive economics associated with provision of dialysis services.
- In October 2013, Satellite Healthcare, a midsized dialysis chain, announced plans to launch a new subsidiary called Satellite Health Plan Inc., a Medicare Advantage plan. Begun in January 2014, this plan offers benefits geared toward dialysis patients.
- In October 2013, NxStage Medical Inc., a manufacturer of home hemodialysis equipment, opened its first dialysis treatment center. The new center is certified to provide both home and in-center dialysis.
- In August 2013, U.S. Renal Care, a midsized dialysis chain, completed its acquisition of Ambulatory Services of America, also a midsized dialysis chain. The acquisition will operate more than 200 facilities and nearly double the number of dialysis patients that U.S. Renal Care will serve. U.S. Renal Care also operates 17 radiation oncology centers.

In public financial filings, the two largest dialysis organizations reported positive financial performance for 2012, including strong treatment (volume) growth, productivity improvements, and cost control initiatives.

These current trends in the profit status and consolidation among dialysis providers suggest that the dialysis industry is an attractive business to for-profit providers and that efficiencies and economies of scale are attained in providing dialysis care. According to one midsized dialysis chain, new clinics become "EBITDA [earnings before interest, taxes, depreciation, and amortization] positive" within an average of 12 months of opening (American Renal Holdings 2011).

Medicare payments and providers' costs

Each year, we assess the relationship between Medicare's provider payments and freestanding providers' costs by considering whether current costs approximate what efficient providers are expected to spend on delivering high-quality care. To make this assessment, we reviewed Medicare expenditures for outpatient dialysis services in

2012 and examined trends in spending under the new PPS. We also reviewed evidence regarding providers' costs under the new PPS.

Medicare payments for outpatient dialysis services under the new PPS

Between 2011 and 2012, the first two years of the new PPS, Medicare spending increased by 6 percent, from \$10.1 billion to \$10.7 billion. During this period, per capita spending increased by 4 percent, from about \$27,700 to nearly \$29,000. The change in total and per capita spending partly reflects (1) the statutory update to the payment rate (2.1 percent for 2012), (2) the growth in the number of beneficiaries (by 2 percent between 2011 and 2012), and (3) the growth in the number of treatments (by 3 percent between 2011 and 2012).

Providers' costs for outpatient dialysis services under the new PPS

To assess the appropriateness of costs for dialysis services paid for under the new PPS, we examine whether aggregate dialysis costs provide a reasonable representation of costs that efficient providers would incur in furnishing high-quality care. For this analysis, we use cost reports for 2011 and 2012, the first two years of the new PPS, submitted by freestanding dialysis facilities. For those years, we look at the growth in the cost per treatment and how total treatment volume affects that cost.

Cost growth under the new PPS Between 2011 and 2012, the cost per treatment rose by 2 percent, from about \$234 per treatment to \$238 per treatment. Variation in cost growth across freestanding dialysis facilities shows that some facilities were able to hold their cost growth well below that of others. For example, between 2011 and 2012, per treatment costs decreased by 4 percent for facilities in the 25th percentile of cost growth and increased by 6 percent for facilities in the 75th percentile.

For the two-year period, the 2 percent cost growth stems partly from rising costs for general and administrative services, which increased by nearly 13 percent and accounted for about one-quarter of the total cost per treatment in both years. General and administrative costs include expenses associated with legal and accounting services, record-keeping and data-processing tasks, telephone and other utilities, home office costs, and malpractice premiums. Between 2011 and 2012, the cost per treatment for general and administrative services rose faster than the other cost categories that increased—labor and supplies. During this period, the cost per treatment

for laboratory services and dialysis drugs, including ESAs and other dialysis drugs that used to be separately billable, declined while capital costs remained relatively unchanged.

Regarding this cost analysis, we do not know whether the costs that facilities include on their cost reports are overstated because CMS has not yet examined the appropriateness of the costs that facilities included (if providers' costs are overstated, the Medicare margin is understated, demonstrating the need for auditing cost reports). The Commission's analysis of the Medicare margin and providers' costs uses only Medicare-allowable costs.

Total volume is correlated with cost per treatment

Cost per treatment is correlated with the total number of treatments a facility provides. The adjusted cost per treatment is inversely related to the total number of treatments a facility provides (Figure 6-6). For this analysis, we adjusted the cost per treatment to remove differences in the cost of labor among areas and included all treatments regardless of payer. Our analysis showed a statistically significant relationship between total treatments and cost per treatment (correlation coefficient equals -0.5 for 2011 and 2012).

Medicare margin for freestanding facilities in 2012

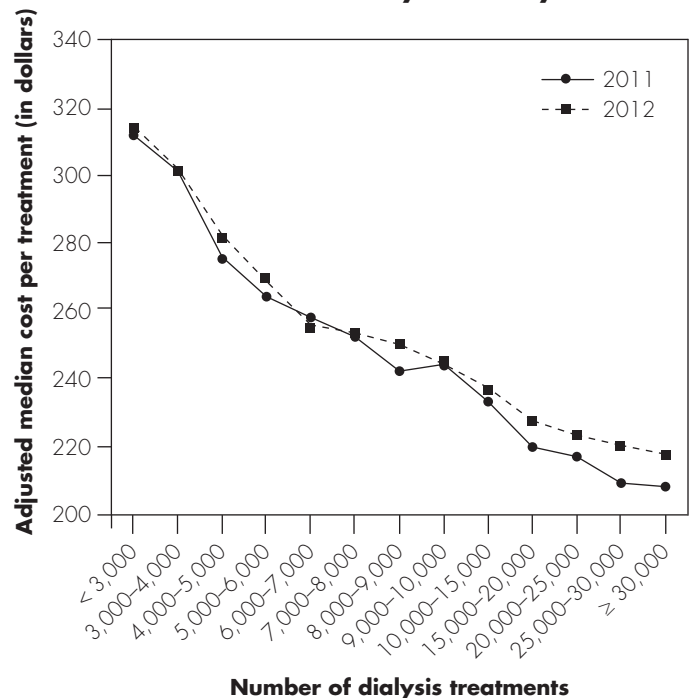
The Commission assesses current payments and costs for dialysis services for freestanding dialysis facilities by comparing Medicare's payments with providers' Medicare-allowable costs. The latest and most complete data available on payments and costs are from 2012. Our analysis includes only facilities that elected to be paid under the new PPS.

For 2012, we estimate that the aggregate Medicare margin was 3.9 percent. The distribution of margins shows wide variation in performance among freestanding facilities (Table 6-4, p. 158). In 2012, one-quarter of facilities had margins at or below -7.9 percent, but half the facilities had margins of at least 2.6 percent, and one-quarter of facilities had margins of at least 11 percent.

Generally, freestanding dialysis facilities' margins vary by the size of the facility; facilities with greater treatment volume have higher margins on average. Urban facilities in 2012 had higher margins than rural facilities (4.7 percent and -0.08 percent, respectively); differences in capacity and treatment volume explain some of the differences observed between urban and rural facilities. Urban dialysis facilities are larger on average than rural facilities with

FIGURE 6-6

Cost per treatment is inversely related to the total treatments a dialysis facility furnishes



Note: Cost per treatment is adjusted to remove differences in the cost of labor. Dialysis treatments include those paid for by all sources (not just Medicare-paid treatments).

Source: MedPAC analysis of 2011 and 2012 cost reports submitted by freestanding facilities to CMS.

respect to number of treatment stations and Medicare treatments provided. In 2012, urban facilities averaged 19 stations, compared with rural facilities' average of 15 treatment stations, and they averaged 8,000 Medicare treatments, compared with rural facilities' average of 5,700 Medicare treatments.

Facilities affiliated with the two largest dialysis organizations tended to have higher margins than other freestanding facilities (4.2 percent and 3.5 percent, respectively). This difference stems from differences in average cost per treatment rather than from provider size. Compared with their counterparts, the average cost per treatment for the two largest dialysis organizations was about 1 percent lower. Provider capacity, as measured by the number of treatment stations, was similar between the two largest dialysis organizations and other freestanding facilities. In 2012, both groups averaged 18 treatment stations.

**TABLE
6-4****Medicare margin in 2012 varies
by type of freestanding provider**

Provider type	Medicare margin	Percent of freestanding dialysis facilities
All	3.9%	100%
Urban	4.7	79
Rural	-0.08	21
Two largest dialysis organizations	4.2	77
All others	3.5	23
Treatment volume (quintile)		
Lowest	-13.0	20
Second	-3.4	20
Third	2.1	20
Fourth	5.2	20
Highest	9.4	20

Source: Compiled by MedPAC from 2012 cost report and outpatient claims submitted by facilities to CMS, the 2012 Dialysis Compare file, and the 2012 CMS Provider of Service file.

Projecting the Medicare margin for 2014

On the basis of 2012 payment and cost data, provider cost growth between 2011 and 2012, and policy changes that are going into effect between 2012 (the year of our most recent margin estimates) and 2015, we project a 2.9 percent aggregate Medicare margin for dialysis facilities in 2014. The policy changes that are included in this projection include:

- statutory updates of 2.3 percent in 2013 and 2.8 percent in 2014;
- other policy changes that resulted in increased payments in 2013 and 2014 of 0.7 percent and 0.6 percent, respectively;
- a 3.3 percent reduction in payments due to rebasing the payment rate in 2014 to account for the reduction in drug use under the new payment PPS; and
- an estimated reduction of 0.29 percent of payments due to the ESRD Quality Incentive Program (QIP) in 2013 and 2014.

This projection does not consider the impact of the sequester, which would lower the margin by about 2 percentage points.

How should Medicare payments change in 2015?

Two major provisions under current law affect the 2015 outpatient dialysis payment rate. First, MIPPA and the Patient Protection and Affordable Care Act of 2010 mandated, beginning in 2012, that the Secretary annually update the outpatient dialysis payment rate by an ESRD market basket index reduced by a productivity adjustment. CMS measures price inflation for ESRD goods and services associated with the new prospective payment bundle. CMS's latest forecast of this index for calendar year 2015 is 2.8 percent. Under current law, the ESRD update is subject to a productivity adjustment, which is currently estimated at 0.3 percent.

Second, the American Taxpayer Relief Act of 2012 rebases the outpatient dialysis payment rate, effective 2014, to reflect more current use of dialysis drugs and biologics. The law mandates that the Secretary (1) rebase the outpatient dialysis payment rate effective 2014 based on changes between 2007 and 2012 in the use of ESAs, other drugs, and biologics, and (2) delay the inclusion of oral-only ESRD-related drugs into the payment bundle until 2016. In 2015, the Secretary intends to offset the (negative) drug utilization adjustment with positive offsets, including the payment update increase and other policy changes, which would result in no change to 2015 total payments compared with 2014 total payments.

In addition to these statutory provisions, the ESRD QIP will have an effect on providers' total payments. For 2015, CMS predicts that the effect of the QIP will decrease total payments by 0.17 percent.

Update recommendation

The evidence on payment adequacy suggests that payments are adequate. It appears that facilities have become more efficient under the new payment method as measured by declining use of injectable dialysis drugs between 2010 and 2012.

RECOMMENDATION 6-1

The Congress should not increase the outpatient dialysis payment rate for calendar year 2015.

RATIONALE 6-1

Most of our indicators of payment adequacy are positive, including beneficiaries' access to care, the supply and

capacity of providers, volume of services, quality of care, and access to capital. Providers have become more efficient in the use of dialysis drugs under the new payment system. The Medicare margin was nearly 4 percent in 2012 and is projected to be nearly 3 percent in 2014.

The decline in dialysis drug use is not unexpected. Under the prior payment method, providers had little incentive to control use of separately billable dialysis drugs, including ESAs, because Medicare paid providers according to the number of units of the drug administered. In addition, the implementation of PPSs in Medicare has historically been characterized by providers quickly reducing use of services included in the payment bundle, resulting in periods of “overpayment”—in which providers benefit from the change in practice patterns and the Medicare program does not realize savings until the payment rate is adjusted. The inpatient hospital, home health, skilled nursing facility, and long-term care hospital PPSs have demonstrated this pattern.

Current law mandates that rebasing begin in 2014, and the Secretary has said that the payment reduction will be phased in over a three- to four-year period. The Commission’s long-held position in many reports and comment letters is that payment rates are not intended to protect each and every provider but instead protect beneficiary access while conserving beneficiaries’ and taxpayers’ resources. In general, the Medicare program should move expeditiously to correct overpayments. At the same time, the payment adjustments should be made such that providers have time to respond to avoid disrupting beneficiary access. The Commission believes that rebasing should be considered year by year and that costs need to be examined broadly, not just for dialysis drugs. Examining the adequacy of Medicare’s payments year by year accomplishes two goals. First, it moves the payment system toward greater accuracy. Second, it protects beneficiary access and gives the Commission the ability to report back to the Congress on any developing issues.

IMPLICATIONS 6-1

Spending

- In 2015, the Secretary intends to offset the negative drug utilization adjustment with positive offsets, including the payment update increase and other policy changes, which would result in no change to 2015 total payments compared with 2014 total payments. The Commission’s update recommendation

is to hold the 2015 payment rate at the 2014 level. Therefore, we estimate that this recommendation would not change federal program spending relative to current Medicare law over one year or five years.

Beneficiary and provider

- We do not anticipate any negative effects on beneficiary access to care. According to our assessment of the payment adequacy indicators, dialysis facilities should be able to accommodate expected cost changes in 2015 with the base payment rate held at 2014 levels. That is, the 2015 base payment rate in the dialysis payment system should be the same as the rate in 2014. This recommendation will increase financial pressure on some providers, but it is not expected to affect providers’ willingness or ability to serve beneficiaries.

Regulatory improvements to the new dialysis PPS

To address three concerns with the new PPS, we recommend that the Congress direct the Secretary to (1) hold providers accountable for poor outcomes related to anemia management; (2) focus the low-volume payment adjustment on protecting facilities critical to beneficiary access; and (3) examine the accuracy of dialysis cost report data under the new PPS. The Secretary has the authority to make these regulatory changes.

The ESRD QIP should hold providers accountable for poor outcomes of anemia management

As discussed earlier, anemia management under the new PPS has changed. Like any PPS, bundled payments create an incentive for providers to furnish fewer services (included in the bundle) than medically necessary. The ESRD QIP in 2013 and beyond does not assess the outcomes associated with the provision of fewer anemia services than medically necessary. The Congress should direct the Secretary to use her authority to develop an ESRD QIP measure that would hold providers accountable for any poor outcomes of anemia management.

Issues and analysis

Under the new PPS, anemia management has changed. As discussed earlier, between 2010 and 2012, ESA use per treatment declined by 40 percent. The measures that

CMS uses to assess the outcomes of anemia management include:

- **Median hemoglobin level**—Between January 2010 and June 2013, this measure has declined from 11.4 g/dL to 10.6 g/dL.
- **Incidence of cardiovascular events**—Between 2007 and 2013, the cumulative share of beneficiaries experiencing stroke, acute myocardial infarction, and heart failure—associated with higher ESA use—generally declined.

The change in anemia management (i.e., the reduction in the use of ESA per treatment) is not unexpected. Under the prior payment method, Medicare paid providers according to the number of units of the drug administered; in other words, the more units provided, the higher the Medicare payment. The new PPS increased the incentive for providers to be more judicious in providing dialysis drugs because they are included in the payment bundle (and thus are a cost center). In addition, the FDA in 2011 called for more conservative ESA dosing. However, the FDA did not provide a specific hemoglobin lower bound considered safe for patients treated with ESAs but said that clinicians could consider starting ESA treatment when the hemoglobin level is less than 10 g/dL and could use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions.

The 2012 ESRD QIP included a measure that assessed the proportion of beneficiaries receiving ESAs with an average hemoglobin level less than 10 g/dL. Beginning in payment year 2013, CMS retired this measure because (1) it could not identify a specific hemoglobin lower bound that has been proven safe for all patients treated with ESAs and (2) the agency believes that it would not be appropriate for the QIP to continue to incentivize ESRD providers to achieve hemoglobin levels above 10 g/dL. Since payment year 2013, the ESRD QIP includes one outcome measure related to anemia management—the proportion of beneficiaries receiving ESAs who have an average hemoglobin level greater than 12 g/dL.

The Commission wants to ensure that beneficiaries continue to have access to effective and appropriate anemia management. Consequently, the ESRD QIP should include a clinical outcome that holds providers accountable for poor outcomes associated with furnishing fewer anemia services than medically necessary. Rather than impose a new administrative burden on providers, the Secretary should, to the extent possible, use data that

are already collected from dialysis facilities. One option for such a measure is assessing the rate of inpatient hospitalizations rather than a specific hemoglobin level (because the FDA has not identified such a level).

CMS could consider using a facility-level measure developed by the agency's contractor that calculates a risk-adjusted standardized hospitalization ratio for admissions. The measure compares the facility's observed number of events with the number of events that would be expected if patients at the facility were subject to the national average rate (University of Michigan Kidney Epidemiology and Cost Center 2013). This measure will be included in the 2014 reports that CMS, through its contractor, provides to each dialysis facility to assess the facility's quality performance to state and national benchmarks.

The low-volume payment adjustment should focus on protecting only facilities critical to beneficiary access

The low-volume payment adjustment under the new PPS is not targeting facilities that might be critical to beneficiary access. The distance requirement in CMS's definition does not prevent facilities that are close to other facilities (e.g., within five miles of one another) from receiving the 18.9 percent payment adjustment to their base rate. Medicare and dialysis beneficiaries would be better served by an adjuster that targets low-volume facilities that are not close to another facility. Only low-volume facilities that are necessary to maintain access—those located in isolated areas—should receive enhanced payment. The Congress should direct the Secretary to use her authority to redesign the payment adjustment so that it considers distance between dialysis facilities.

Issues and analysis

CMS defines a low-volume facility as one that provides fewer than 4,000 treatments (Medicare and non-Medicare) in each of the three years before the payment year and has not opened, closed, or received a new provider number because of a change in ownership during the three-year period.²³ For existing facilities (i.e., those that were certified for Medicare participation as of December 31, 2010), CMS's definition does not impose a distance requirement between the facility that receives the low-volume adjustment and the next closest facility. However, for new facilities (i.e., those that were certified on or after January 1, 2011), for purposes of determining eligibility for the adjustment, the number of treatments is equal to the sum of the number of treatments provided by a facility

**TABLE
6-5****Distance of low-volume dialysis facilities to nearest facility, by provider type, 2012**

	Percent of low-volume facilities	Median miles to nearest facility	Percent of low-volume facilities within 5 miles of nearest facility
All low-volume facilities	100%	7	48%
Freestanding	81	4	52
Hospital based	19	24	32
Urban	52	2	72
Rural	48	25	22
Two largest dialysis organizations	61	4	52
All others	39	18	41

Source: MedPAC analysis of 2012 claims submitted by dialysis facilities to CMS.

and any other facilities under common ownership that are within 25 road miles from the facility in question.

Our analysis of 2011 and 2012 Medicare claims data shows that 363 facilities received the low-volume payment adjustment in 2012, an increase from 2011 of nearly 10 percent. In 2012, 81 percent of low-volume facilities were freestanding, 19 percent were hospital based, 52 percent were located in urban areas, and 48 percent were located in rural areas (Table 6-5).

Some facilities receiving the low-volume adjustment were close to other dialysis facilities. Of the facilities that received the low-volume payment adjustment in 2012, nearly 50 percent were within five miles of the next facility. The median distance between the facility receiving the adjustment and the next facility was seven miles. Facilities that were freestanding, urban, and affiliated with the two largest dialysis organizations tended to be closer to the next facility than facilities that were hospital-based, rural, and not affiliated with those organizations (Table 6-5). For example, the median distance between urban facilities and the next closest facility was 2 miles; for rural facilities, the median distance to the next closest facility was 25 miles. Our analysis of the proximity of low-volume facilities to other facilities in 2011 generally found similar results (Medicare Payment Advisory Commission 2013).

In 2012, 14 facilities that received the low-volume payment adjustment had the same street address as another dialysis facility that did not receive the low-volume payment adjustment. Most of the 14 facilities had

the same ownership as the facility with the same street address.

In addition to the lack of a distance requirement for facilities certified before 2011, the design of the low-volume payment adjustment also raises concerns because it gives facilities an incentive to limit services to avoid reaching the 4,000 treatment threshold (the so-called “cliff” effect) (Government Accountability Office 2013). A payment approach that decreases the payment adjustment as facility volume increases might reduce this incentive.

This payment adjustment is targeting facilities that have on average higher cost per treatment than other facilities, as specified by MIPPA.²⁴ In 2011 and 2012, the adjusted cost per treatment for freestanding facilities that received the low-volume payment adjustment was about 20 percent greater than for freestanding facilities without the adjustment.

Dialysis facilities’ cost report data under the new PPS should be examined for accuracy

CMS has not yet examined the appropriateness of the costs that facilities include in their cost reports under the new PPS. The Congress should direct the Secretary to use her authority to conduct audits that assess the accuracy of dialysis facilities’ cost report data.

Issues and analysis

It is important to examine the accuracy of facilities’ cost reports for several reasons. First, it is basic fiscal management to ensure that facilities’ cost reports are

accurate. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Medicare cost principles are designed to ensure that Medicare pays reasonable expenses related to patient care. Second, it has been more than 10 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change.

Third, historically, facilities' cost reports have included costs that Medicare does not allow. Analysis of previous audits (in 1988, 1991, 1996, and 2001) of dialysis facilities' cost reports found that facilities' allowable costs ranged from 90 percent to 96 percent of costs submitted. CMS's recent audit of a sample of 100 home health agency cost reports demonstrates the importance of validating these data. The agency found that agencies in the audit sample overstated their costs by an average of about 8 percent (Centers for Medicare & Medicaid Services 2013b).

Medicare's contractors (e.g., fiscal intermediaries) and the Department of Health and Human Services' Office of Inspector General have conducted past audits of dialysis facilities' cost reports (Government Accountability Office 1993). Medicare administrative contractors conducted the recent audit of cost reports submitted by home health agencies. To ensure that audits are thorough and complete, auditors should (1) evaluate whether the reported costs are supported by facilities' accounting records; (2) assess whether the costs are reasonable and related to patient care; and (3) assess the appropriateness of transactions with affiliated entities—called related organizations—that are under common ownership or control.

Recommendation

Regulatory changes are needed to include a measure in the ESRD QIP that holds providers accountable for poor outcomes related to providing fewer anemia services than medically necessary, redesign the low-volume payment adjustment, and assess the accuracy of dialysis facilities' cost report data under the new PPS.

RECOMMENDATION 6-2

The Congress should direct the Secretary to:

- **include a measure that assesses poor outcomes related to anemia in the End-Stage Renal Disease Quality Incentive Program.**
- **redesign the low-volume payment adjustment to consider a facility's distance to the nearest facility.**
- **audit dialysis facilities' cost report data.**

RATIONALE 6-2

This recommendation would hold providers accountable for the poor outcomes of anemia, target the low-volume payment adjustment only to facilities that are isolated, and help ensure that dialysis facilities' cost reports are accurate.

IMPLICATIONS 6-2

Spending

- We expect that the spending implications of this recommendation will be budget neutral. This recommendation would redistribute payments to low-volume facilities. We are unable to calculate the impact of the first and third provisions of this recommendation.

Beneficiary and provider

- This recommendation might improve the quality of anemia management. It should help ensure that, under the new PPS, beneficiaries' access to care is maintained at isolated, low-volume facilities. The recommendation is not expected to affect providers' willingness or ability to serve beneficiaries. Payments would decrease for providers who currently receive the low-volume payment adjustment but are in close proximity to other facilities and would increase for providers who have lower treatment volumes, are not in close proximity to other facilities, but currently do not receive the low-volume payment adjustment. ■

Endnotes

- 1 The term *dialysis drugs* refers to the medications used to treat ESRD.
- 2 In this chapter, the term *beneficiaries* refers to individuals covered by Medicare, and *patients* refers to individuals who may or may not be covered by Medicare. Most dialysis patients are covered by Medicare as either the primary or secondary payer.
- 3 The total number of individuals on dialysis in 2012 was estimated by inflating the 2011 United States Renal Data System's number of dialysis patients by the annual growth in the dialysis population between 2006 and 2011.
- 4 This estimate remained relatively steady between 2006 and 2011.
- 5 According to CMS's *Medicare Managed Care Manual*, an individual who receives a kidney transplant and who no longer requires a regular course of dialysis to maintain life is not considered to have ESRD for purposes of MA eligibility. Such individuals may elect to enroll in an MA plan, if they meet other applicable MA eligibility requirements.
- 6 ESRD patients include those who initiate dialysis or receive a kidney transplant.
- 7 The incidence of ESRD increased by 1 percent per year for individuals 19 years or younger. In 2011, this age group accounted for only 1 percent of new ESRD cases (United States Renal Data System 2013).
- 8 For individuals entitled to Medicare based on ESRD, Medicare coverage does not begin until the fourth month after the start of dialysis, unless the individual had a kidney transplant or began training for self-care, including those dialyzing at home.
- 9 *Higher levels of residual kidney function* refers to patients with an estimated glomerular filtration rate (a measure of residual kidney function calculated using the Chronic Kidney Disease Epidemiology Collaboration formula) above 15 milliliters per minute per 1.73 square meters (United States Renal Data System 2013). Clinicians use the estimated glomerular filtration rate to assess residual kidney function; lower values of this measure suggest reduced residual kidney function.
- 10 In 2012, the American Kidney Fund provided assistance to one out of every five dialysis patients for health insurance premiums and other treatment-related expenses (American Kidney Fund 2014).
- 11 No later than November 1, 2010, dialysis facilities could have elected to be reimbursed 100 percent by the new PPS. Between 2011 and 2013, CMS paid facilities that did not elect to be reimbursed by the new PPS by a blended payment rate composed of the older payment method (basic case-mix-adjusted composite rate payment system) and the new PPS. In 2012, we estimate that 95 percent of all facilities were paid under the new PPS instead of the four-year transition rate. Facilities that received Medicare certification after January 1, 2011, are paid under the new PPS.
- 12 In this chapter, the term *providers* refers to freestanding and hospital-based dialysis facilities. Technically, under Medicare law, freestanding dialysis facilities are suppliers and hospital-based dialysis facilities are providers.
- 13 In 2011, Fresenius acquired Liberty Dialysis and DaVita acquired DSI Renal.
- 14 According to CMS's *Provider Reimbursement Manual*, a chain organization consists of a group of two or more health care facilities or at least one health care facility and any other business or entity owned, leased, or, through any other device, controlled by one organization (Centers for Medicare & Medicaid Services 2012).
- 15 These drug classes accounted for nearly all dialysis drug spending (about 97 percent) in 2010, the year before the start of the new payment method.
- 16 According to OIG, in 2009, most (93 percent) Medicare-certified dialysis facilities had protocols in place for administering ESAs (Office of Inspector General 2009). For dialysis facilities with protocols in place for administering ESAs, physicians may approve the protocols as patients' standing orders.
- 17 In March 2007, the FDA included a "black box warning" on ESA drug labels advising physicians that the risks of death and serious cardiovascular events are greater when ESAs are administered to achieve higher target hemoglobin levels and that dosing should be individualized to maintain hemoglobin levels between 10 g/dL and 12 g/dL.
- 18 Anemia is measured by a blood test to check the level of hemoglobin, the protein that carries oxygen in red blood cells.
- 19 Blood transfusions are of concern to patients because they (1) carry a small risk of transmitting blood-borne infections to the patient, (2) may cause some patients to develop a reaction, and (3) are costly and inconvenient to patients. Blood transfusions are of particular concern for patients seeking

kidney transplantation because they increase a patient's alloantigen sensitization, which can require a patient to wait to receive a transplant.

- 20 USRDS data show that the percent of dialysis patients with one or more transfusion events remained relatively steady between 2003 and 2009 (United States Renal Data System 2011, United States Renal Data System 2010).
- 21 MIPPA does not permit dialysis facilities to bill for KDE services.
- 22 Under contract to CMS, Arbor Research Collaborative, in collaboration with the University of Michigan Kidney and

Epidemiology Cost Center, provides each dialysis facility a report that compares the facility's quality performance with state- and national-level rates. Kidney transplantation was one of the measures included in the 2013 report (University of Michigan Kidney Epidemiology and Cost Center 2013).

- 23 Pediatric dialysis treatments are not eligible for the low-volume adjustment.
- 24 MIPPA required the new dialysis PPS to "include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services."

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